

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D1034068	(X3) Date Survey Completed 07/06/2023
Name of Provider or Supplier Arkansas Gastroenterology	Street Address, City, State 3401 Springhill Dr, Suite 400, North Little Rock, AR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Through observations made during a tour of the laboratory, review of manufacturer's instruction manual, review of the laboratory's temperature and humidity records, and interviews with staff, it was determined the laboratory humidity was below the manufacturer's requirement for the laboratory's Tissue-Tek DRS 2000 Slide Stainer and Sakura Tissue-Tek TEC 5. Survey findings include: A) During a tour of the laboratory on 7/7/2023 at 11:30 a.m., Tissue-Tek DRS 2000 Slide Stainer and Sakura Tissue-Tek TEC 5 was observed in the main laboratory. B) Review of the manufacturer's instruction manual for Tissue-Tek DRS 2000 Slide Stainer and Sakura Tissue-Tek TEC 5 normal operating humidity range is 30%-85%. C) Review of the Laboratory Temperature Log revealed conditions of operating requirement listed as "Room Temp 55-80F and Room Humidity 10%-80% ". D) Review of the laboratory's room temperature and humidity log for January, February, March, April, September, October, November, and December of 2022 revealed 93 days humidity below 30%. E) Review of the laboratory's room temperature and humidity log for January, February, March, April, and May of 2023 revealed 39 days humidity below 30%. F) In an interview on 7/7/2023 at 12:49 p.m. the laboratory staff member (# 2 on the CMS 209 form) confirmed that the Tissue-Tek DRS 2000 Slide Stainer and Sakura Tissue-Tek TEC 5 was in use 132 days below 30% humidity.</p>